Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Letter to the Editor

Evaluating the newly developed BioFire COVID-19 test for SARS-CoV-2 molecular detection

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It was not until 24 March 2020 that the newly developed BioFire coronavirus disease 2019 (COVID-19) test (BioFire Defense, Salt Lake City, UT, USA) for PCR-based detection of RNA from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in clinical samples received a US Food and Drug Administration emergency-use authorization (https://www.fda.gov/media/136356/download). It is thus not surprising that no published studies to date have evaluated the BioFire COVID-19 test in clinical microbiology practice.

We compared the performance of BioFire COVID-19 test with that of Quanty COVID-19 assay (Clonit, Milan, Italy), which also provides quantitative results, for detection of SARS-CoV-2 RNA in nasal/oropharyngeal (N/OP) patient samples. Both molecular tests detect SARS-CoV-2 specifically, with the first targeting two viral open reading frame (ORF) sequences (ORF1ab and ORF8)—in three independent PCR assays—and the second targeting three viral nucleocapsid (N) sequences (N1, N2 and N3). Such comparison is essential for defining the cause of potential false-negative results [1], which may undermine the clinical utility of various molecular diagnostic tests available currently [2,5].

We analysed the results of 120 N/OP samples tested with both the BioFire COVID-19 test and the Quanty COVID-19 assay. Samples that had been kept frozen at −70°C until testing to ensure RNA integrity were randomly selected from among those that were SARS-CoV-2 positive ($n = 86$) and negative ($n = 34$), as tested with the Allplex 2019-nCoV assay (Arrow Diagnostics, Genova, Italy) [3], and then confirmed (as positive or negative respectively) by a real-time PCR assay (here used as the reference method) based on the Corman et al. method [4]. The agreement between the BioFire COVID-19 test and Quanty COVID-19 assay was 95.0% (114/120) for overall results and 100% (34/34) for negative results. Eighty (93.0%) of 86 positive samples yielded results with the BioFire COVID-19 test that matched those with the Quanty COVID-19 assay. For six remaining positive samples, BioFire COVID-19 test results did not match those with the Quanty COVID-19 assay. As shown in Supplementary Table S1, two of six samples—falsely negative by BioFire COVID-19 test—had no detections in all three assays (hence interpreted as 'not detected'), whereas four samples initially yielded detection in only one assay (hence interpreted as 'equivocal') but resulted as 'not detected' at retesting. Interestingly, virus loads (expressed as RNA copies/mL) of the six samples were 2.20×10^1 to 1.60×10^2. However, these loads were below the limit of detection of 3.30×10^2 RNA copies/mL estimated for the BioFire COVID-19 test (https://www.biofiredefense.com/covid-19test/). In 80 samples with results agreeing between the assays, the median (interquartile range) virus load was 7.89×10^3 (2.48×10^3–2.75×10^5) RNA copies/mL, which was consistent with an average (range) value of 1.24×10^8 (3.82×10^2–7.83×10^9) RNA copies/mL. Compared to the reference method, the BioFire COVID-19 test sensitivity, specificity, positive predictive value and negative predictive value (with their 95% confidence intervals) were 93.0 (85.4–97.4), 100.0

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(89.7–100.0), 100.0 (95.5–100.0) and 85.0 (70.2–94.3), respectively.

These findings suggest that the lower analytical sensitivity of the BioFire COVID-19 test might have caused false-negative results in our study. Consequently, compared to molecular tests such as the Quanty COVID-19 assay, the analytical sensitivity shown by BioFire COVID-19 test would result in a slight reduction in its clinical sensitivity in COVID-19 diagnosis. Additionally, 'equivocal' results that at repeated testing with the BioFire COVID-19 test are claimed as 'not detected' may actually be truly positive, but this requires further investigation. Relying on fully automated FilmArray platforms, BioFire COVID-19 test provides results in approximately 45 minutes from N/OP sample collection. Thus, the possibility of shortening the time to results merits consideration when deciding which SARS-CoV-2 molecular test to implement in the clinical microbiology laboratory.

Transparency declaration

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cmi.2020.07.026.

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